EXHIBIT S

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO CASE CONSOLIDATION: **Terreski Mullins, et al., v. Ethicon, Inc., et al.** **Case No. 2:12-CV-02952**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION AND MEMORANDUM TO EXCLUDE THE OPINIONS AND TESTIMONY OF DEFENDANT ETHICON, INC.'S EXPERT STEVEN MACLEAN, PH.D., P.E.

Dr. Steven MacLean, Ph.D., P.E., is a polymer scientist and engineer who has been actively practicing in his field for the past 20 years. *See* Motion Ex. 1, Expert Report of Dr. Steven MacLean ("General Report"), at 7. Despite Dr. MacLean's substantial education, training, and experience practicing in the field of polymer science and engineering, Plaintiffs seek to preclude him from offering opinions to assist the jury in this case.

Ethicon designated Dr. MacLean, in part, to rebut the opinion offered by Plaintiffs' experts that the PROLENE used in TVT is subject to oxidative degradation in the human body. Dr. MacLean's opinions on these issues are set forth in two separate expert reports.

Dr. MacLean's Microscopy Report

Dr. MacLean's Microscopy Report describes a simple control experiment designed to assess the validity of a hypothesis relied upon by Dr. Vladimir Iakovlev—Plaintiffs'

pathologist—as the basis of all his degradation opinions in this case, which he failed to test. Specifically, Dr. Iakovlev opines that PROLENE oxidizes and degrades *in vivo* such that cracks in the degraded PROLENE trap histological stains, forming a purple "bark" that Dr. Iakovlev can detect using light microscopy. *See* Response Ex. A, Iakovlev Expert Report at 8-9, 17-18 (discussing degradation theories). Although Dr. Iakovlev offers numerous degradation opinions, all of them are dependent on his alleged detection of a degraded bark layer on the surface of PROLENE.

Dr. Iakovlev admits that his hypothesis is capable of being tested by intentionally oxidizing pristine PROLENE to determine (i) whether it degrades and, if so, (ii) whether the outer bark traps stain (*i.e.*, is visible as purple "bark"). *See* Response Ex. B, Iakovlev 9/11/2015 Dep. at 31:14-46. Dr. Iakovlev also admits that while he is currently conducting such a test, (*id.*), it remains incomplete at this time (*id.* at 31:14-25).

Dr. MacLean, on the other hand, ran the control experiment Dr. Iakovlev failed to conduct. *See generally* Motion Ex. 2, Expert Report of Dr. Steven MacLean – Microscopy ("Microscopy Report"). Specifically, Dr. MacLean and a team of scientists working at his direction, including Dr. Stephanie Benight, intentionally oxidized PROLENE mesh samples using two distinct methods, and then used the same sample preparation protocol and histological stains used by Dr. Iakovlev to determine whether oxidized PROLENE traps the stains. *See id.* at 8-18. It does not.

Dr. MacLean designed the experiment to incorporate two distinct methods for intentionally oxidizing the PROLENE samples. *Id.* at 8-9. First, in order to ensure that his team had at least some oxidized samples of PROLENE on which to conduct tests, Dr. MacLean's team subjected one batch of PROLENE samples to ultraviolet radiation ("QUV"), which is

widely recognized in scientific literature to oxidize polypropylene, including PROLENE. *Id.*; *See* Motion Ex. 7, Benight 10/13/2015 Dep. at 214:6-13 (explaining that they conducted a QUV treatment "because that's covered in over hundreds of literature articles . . . including intentionally oxidizing polymer samples"). Second, Dr. MacLean's team exposed a separate batch of PROLENE samples to an oxidative medium using the same chemical oxidation protocol used by Drs. Scott Guelcher and Russell Dunn, experts for plaintiffs in pelvic mesh litigation. *See* Motion Ex. 2, Microscopy Report at 8; Motion Ex. 7, Benight Dep. at 65:14-18.

Dr. MacLean and his team conducted scanning electron microscopy ("SEM") on the samples, and found that while the QUV-treated samples exhibited significant surface cracking, the chemically oxidized samples did not. *See* Motion Ex. 2, Microscopy Report at 9-10.

Dr. MacLean's team then submitted PROLENE samples treated using both oxidation methods for processing and staining according to the protocol established by Dr. Iakovlev. *Id.* at 8-9. Their analysis of these samples proved that even intentionally oxidized PROLENE does not trap or otherwise hold histological stains. *Id.* at 12-15.[1] Thus, Dr. MacLean and his team—using a valid and repeatable scientific methodology—showed that the lynchpin of Dr. Iakovlev's degradation theories is flawed and unreliable.

Dr. MacLean's General Report

Separately, Dr. MacLean submitted a General Report in which he opines, *inter alia*, that PROLENE does not degrade *in vivo*. *See* Motion Ex. 1, General Report at 61-62. Specifically, Dr. MacLean discusses the physical and chemical characteristics of polypropylene and

[1] Dr. MacLean's investigation also shows that manipulation of a microscope's polarizers when viewing PROLENE can produce a bark along the surface of the fiber. *See id.* at 12-13, 15-17 (explaining that slides for microscopy are prepared using a microtome to slice the mesh fibers, which causes variations in the thickness of the fibers in the slide which "can create edge artifacts under polarized light").

PROLENE, as well as the chemical effects of oxidation and sample preparation on those substances. *Id.* at 10-23. The General Report also sets forth Dr. MacLean's analysis of the relevant scientific literature and Ethicon studies on which he bases his opinion that PROLENE does not degrade following implantation *Id.* at 24-32, 35-46. Finally, Dr. MacLean's General Report explains in detail that the degradation opinions offered by Plaintiffs' experts Drs. Vladimir Iakovlev, Howard Jordi, and Scott Guelcher are not based on scientifically reliable evidence. *Id.* at 47-60.

Plaintiffs challenge Dr. MacLean's testimony on three main grounds. First, Plaintiffs claim that Dr. MacLean is not qualified to offer biocompatibility and regulatory opinions in this case.

Second, Plaintiffs assert that Dr. MacLean's opinions based on his control experiment are unreliable because he allegedly failed to (i) develop a written protocol, (ii) maintain proper laboratory documentation, (iii) use a sufficient sample size or conduct statistical analysis, and (iv) conduct SEM or FTIR analysis on the samples subjected to histological staining.

Third, Plaintiffs assert that Dr. MacLean's opinions based on Ethicon's Seven-Year Dog Study are unreliable because the study's molecular weight analysis compared PROLENE sutures of different diameters.

All of Plaintiffs' arguments are without merit, and this Court should deny Plaintiffs' motion.

ARGUMENT

I. Dr. MacLean is Qualified to Offer Opinions Regarding Questions of Polymer Science.

Dr. MacLean is a polymer scientist and engineer who has actively practiced in his field for 20 years. *See* Motion Ex. 1, Expert Report of Dr. Steven MacLean ("General Report"), at 7.

Dr. MacLean has a B.S. and M.E. in Mechanical Engineering, an M.S. in Material Science and Engineering, and a Ph.D. in Materials Science. *Id.* Dr. MacLean's work includes the development of novel polymer formulations to combat known modes of degradation, including oxidation. *Id.* He is a registered Professional Engineer in New York and Maryland, and a Senior Member of the Society of Plastics Engineers. *Id.* Through his education, training, and more than 15 years working at General Electric Plastics and SABIC Innovative Plastics, Dr. MacLean developed expertise in polymer analysis using various methods, including infrared spectroscopy, chromatography, and mass spectrometry, as well as optical, scanning electron microscopy, and transmission electron microscopy. *Id.* at 7-8.

Notably, Plaintiffs do not challenge Dr. MacLean's credentials and experience as a polymer scientist and engineer. Rather, in a misguided attempt to cast doubt on Dr. MacLean's qualifications, Plaintiffs list numerous disciplines and actions in which Dr. MacLean never claimed to have expertise, and point to issues about which Dr. MacLean never sought to opine. *See* Motion at 4-9. For example, Dr. MacLean never claimed to be a veterinarian or a pathologist (*id.* at 5), and has never offered opinions regarding cytotoxicity in this case (*id.* at 7). Thus, most of the issues identified by Plaintiffs have no bearing on Dr. MacLean's opinions in this case, and amount to little more than a straw man.[2]

[2] Plaintiffs overreach to the extent they seek to argue that Dr. MacLean lacks sufficient expertise to opine on issues of chemistry as they relate to polymer science. *See* Motion at 7. As Dr. MacLean explained at deposition, he is an expert in the chemical interactions of polymers and organic materials based on his substantial education, training, and experience in polymer science. *See* Motion Ex. 4, MacLean 09/29/2015 Dep. at 377:3-15. Although Dr. MacLean agreed that he is not an expert in chemistry, (*id.* at 81:13-20), he explained that to qualify as such an expert, one must "have advanced degrees, specifically in chemistry," as well as significant training and professional experience in chemistry. *Id.* at 376:21-377:2. Such advanced knowledge and training in chemistry is not necessary in the practice of polymer science or to support Dr. MacLean's opinions in this case. *Id.* at 377:13-379:5.

Dr. MacLean is a polymer scientist and engineer with substantial education, training, and experience practicing in his field. *See, e.g.*, Motion Ex. 1, General Report at 7-9. In this case, he will offer opinions regarding questions of polymer science consistent with his expert reports and deposition testimony. He will not offer opinions regarding biocompatibility or regulatory issues in this case.[3]

II. Dr. MacLean's Opinions Are Reliable Because His Experiment Was Conducted In Accordance With Proper Scientific Procedures.

A. Dr. MacLean and His Team Followed Three Separate Protocols In Conducting the Experiment.

In conducting the control experiment, Dr. MacLean and his team followed three separate protocols for different aspects of the experiment. First, to assess the alleged chemical oxidation of PROLENE, they followed a protocol published by Drs. Scott Guelcher and Russell Dunn—experts for Plaintiffs in pelvic mesh litigation. *See* Motion Ex. 2, Microscopy Report at 8; Motion Ex. 4, MacLean Dep. at 302:2-5; Motion Ex. 7, Benight Dep. at 65:14-18; 90:21-24; 150:19-24. Through this protocol, Drs. Guelcher and Dunn purportedly induced chemical oxidation of PROLENE samples.

Second, in order to ensure that some of the PROLENE samples used in their experiment were actually oxidized, Dr. MacLean and his team followed a protocol involving exposure of the PROLENE samples to ultraviolet light, or "QUV", which is known to oxidize PROLENE. *See*

[3] To the extent Plaintiffs choose to cross-examine Dr. MacLean on industry accepted standards and procedures used to assess the biocompatibility of polymeric material, Dr. MacLean has the relevant education, training and experience to address those issues. As discussed in Dr. MacLean's Report, Dr. MacLean was one of the technical architects that designed and developed GE/SABIC's healthcare resin portfolio while serving as the Director of Global Agency Relations and Product Safety. *See* Motion Ex. 1, General Report at 8-9 & Appendix A. Part of Dr. MacLean's work in that capacity included ensuring that commercialized resin grades within the GE/SABIC healthcare portfolio were assessed for biocompatibility using industry accepted test methods, including ISO 10993 Biological Evaluation of Medical Devices standards. *Id.* at 9.

Motion Ex. 2, Microscopy Report at 8; Motion Ex. 7, Benight Dep. at 214:6-13 (explaining that they conducted a QUV treatment "because that's covered in over hundreds of literature articles . . . including intentionally oxidizing polymer samples"). Specifically, they used a protocol presented by Dr. Maureen Reitman, *et al.*, which provided a specific irradiance profile and temperature for the experiment. *Id*. at 214:6-13; 232:10-17. Through this protocol, Dr. MacLean and his team were able to detect "clear evidence of cracking on the outside surface" of the PROLENE fibers. *See* Motion Ex. 4, MacLean Dep. at 295:5-16.

Third, to determine whether intentionally oxidized PROLENE could trap histological stains, Dr. MacLean and his team followed the slide preparation and staining protocol used by Dr. Iakovlev. *See* Motion Ex. 2, Microscopy Report at 9, 20-21; Motion Ex. 4, MacLean Dep. at 404:18-405:17; Motion Ex. 7, Benight Dep. at 153:16-22; 258:12-23. Through this protocol, Dr. Iakovlev has allegedly found that histological stains are trapped in the cracks of the degraded outer layer of PROLENE, enabling him to visualize the degradation through microscopy.

Finally, Dr. MacLean's team followed procedures to ensure that all test results from samples that were oxidized and then stained can be traced and readily identified in the laboratory documentation for the experiment. *See* Motion Ex. 4, MacLean Dep. at 374:9-22; Motion Ex. 7, Benight Dep. at 226:11-228:22. Dr. MacLean's team recorded all steps taken during the experiment, including the labeling of samples and the tests conducted on each. *See* Motion Ex. 7, Benight Dep. at 226:19-24; *see also id.* at 152:4-153:15; 181:8-20; 182:15-183:25. Throughout the experiment, Dr. MacLean and his team maintained a "one-to-one correspondence" between the samples and their respective test results and microscopy images. *See* Motion Ex. 4, MacLean Dep. at 375:16-376:3. All of this information was produced to Plaintiffs in this case. *Id.* at 374:9-

20. In addition, Dr. MacLean's team preserved all samples that were used in the staining and microscopy experiment. *See* Motion Ex. 4, MacLean Dep. at 375:3-5.

As such, Dr. MacLean's team—as well as Plaintiffs—can "trace back from the actual fibers that were either chemically or UV oxidized all the way through to the microtome samples that were stained and imaged by optical microscopy." *Id.* at 375:16-376:3. In other words, another scientist can not only replicate, but actually re-create Dr. MacLean's experiment. *Id.* at 376:4-15.

Dr. MacLean and his team meticulously applied these protocols in their control experiment. *See* Motion Ex. 7, Benight Dep. 255:23-256:17, 258:12-23; *see also id.* at 19:14-18; 118:8-21; 229:6-23. In so doing, they conducted the testing that Dr. Iakovlev should have—but did not—conduct before reaching a conclusion. *See* Motion Ex. 4, MacLean Dep. at 72:24-73:2; Motion Ex. 7, Benight Dep. at 19:14-23.

Despite the use of well-defined protocols by Dr. MacLean and his team, Plaintiffs argue in their motion that Dr. MacLean's opinions are unreliable because he did not transcribe these three protocols into a single document at the outset of the experiment. *See* Motion at 14, 15-18. But as this Court has explained, it is not the writing of, but the "[v]igorous *adherence* to protocols and controls [that] are the hallmarks of 'good science.'" *Sanchez*, 2014 WL 4851989 at *28. There is no principle of science that requires a scientist to re-write existing protocols in order for their work to be scientifically valid. Tellingly, Plaintiffs identify no authority for their assertion to the contrary.

Plaintiffs also suggest that the methods used by Dr. MacLean's team prevented them from properly accounting for the samples and testing during the experiment. *See* Motion at 16-18. Plaintiffs ignore the fact that the procedures employed by Dr. MacLean's team ensures that

another scientist can readily reproduce and verify the experiment. *See, e.g.,* Motion Ex. 4, MacLean Dep. at 376:4-15.

Dr. MacLean and his team adhered to the scientific method and rigorously applied the protocols defined by Dr. Guelcher, Dr. Iakovlev, and Dr. Reitman in conducting their experiment.[4] In so doing, they produced reliable results that, as discussed below in Section II.B., are readily capable of being reproduced by other scientists. Accordingly, the Court should deny Plaintiffs' motion.

B. Dr. MacLean and His Team Properly Maintained Laboratory Documentation Throughout the Experiment.

For courts and scientists alike, a crucial aspect of the validity of testing is its ability to be repeated and verified by other scientists. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 593 (1993) ("Scientific methodology today is based on generating hypotheses and testing them *to see if they can be falsified:* indeed, this methodology is what distinguishes science from other fields of human inquiry.") (emphasis added). As such, scientists recognize that they must maintain proper laboratory documentation to "ensure[] that the experiments that are performed are recorded so that another reasonable scientist can repeat the work if needed." *See* Motion Ex. 7, Benight Dep. at 223:2-17.

During Dr. MacLean's experiment for this case, his team recorded all of their actions and procedures in laboratory documentation. *See* Motion Ex. 4, MacLean Dep. at 374:9-375:2;

[4] Plaintiffs' reliance on this Court's opinion in *Sanchez v. Boston Scientific Corp.* is misplaced. *See* Motion at 15-16. In *Sanchez*, there was no showing that Dr. Mays established or adhered to a consistent testing protocol. *Id.* at *27. In addition, the Court found that Drs. Mays and Gido followed an unpublished, completely subjective standard for their cracking analysis. *Id.* Furthermore, the Court noted that the experts in that case had committed various errors in their testing and report for which they could not account. *Id.* at *27-28. In striking contrast, Dr. MacLean and his team followed clearly defined protocols throughout their experiment, and produced reliable and verifiable results.

Motion Ex. 7, Benight Dep. at 223:18-21. The laboratory documentation includes all of the steps taken during the experiment, the testing protocols, a log of test specimens, and the photographs, images, and micrographs taken during the testing.[5] *See* Motion Ex. 4, MacLean Dep. at 11:15-21; Motion Ex. 7, Benight Dep. at 226:2-24. This laboratory documentation exists so that another scientist can repeat and verify all of the work conducted during the experiment. *See* Motion Ex. 4, MacLean Dep. at 374:23-375:2; Motion Ex. 7, Benight Dep. at 223:2-17; 227:4-11. All of the laboratory documentation for Dr. MacLean's experiment was provided to Plaintiffs in this case. *Id*. at 223:22-224:1.

In addition, due to the methodology employed by Dr. MacLean and his team, a scientist can re-create and verify his experiment using Dr. MacLean's original specimens. This is because Dr. MacLean and his team maintained a "one-to-one correspondence" between their test samples and the micrographs, enabling a scientist to use the laboratory documentation to trace their results back to the samples. *See* Motion Ex. 4, MacLean Dep. 375:16-376:3. As a result, other scientists—including Plaintiffs' experts—can repeat and confirm Dr. MacLean's work. *Id.* at 376:4-15.

Despite these steps taken by Dr. MacLean and his team to ensure that their work is repeatable, Plaintiffs assert that Dr. MacLean's opinions are unreliable because his team failed to "record . . . the steps or procedures performed by each member of the team during the experiment." *See* Motion at 14, 18. Tellingly, Plaintiffs do not address any of the laboratory

[5] Although Plaintiffs suggest that the laboratory documentation practices of Dr. MacLean's team were insufficient because they did not specify the individual who conducted a specific task, Dr. Benight explained that "it's not important who does it" because it is only the "conditions that the experiment were performed at [that] are relevant for another scientist to repeat the experiment." *See* Motion Ex. 7, Benight Dep. at 251:13-23.

documentation produced in conjunction with the depositions of Drs. MacLean and Benight, or their related testimony.

Instead, Plaintiffs resort to arguing that Dr. Benight failed to account for certain steps in the testing based on out-of-context deposition testimony. *See* Motion at 18 n. 65. Plaintiffs conveniently ignore the fact that Dr. Benight repeatedly testified that while she could not recall certain information at deposition, all of the requested information was recorded in the lab documentation which had been provided to Plaintiffs. *See, e.g.*, Motion Ex. 7, Benight Dep. at 44:15-45:4 (testifying that although she did not know the number of samples cut, information regarding sample numbers and preparation "is documented in the documents that were provided to you electronically"); 63:15-22 (explaining that she would "have to look at the production documents" to identify the samples exposed to QUV); 130:4-14 (testifying that the documentation of the QUV-treated samples sent to Histion for processing is contained in the Histion chain of custody documents).

Plaintiffs' arguments fail because Dr. MacLean and his team maintained laboratory documentation and materials that enable other scientists to not only repeat their work, but to do so with Dr. MacLean's own specimens. The Court should reject Plaintiffs' unsupported attempt to undermine the results of a test their expert failed to conduct.

C. Dr. MacLean's Control Experiment Incorporated a Scientifically Proper Sample Size.

Plaintiffs argue that Dr. MacLean's opinions are unreliable because he used an insufficient sample size. *See* Motion at 14, 18. They claim that because Dr. MacLean submitted only one mesh sample to Histion for histological processing, the results of his experiment are not

valid. *Id.* at 14. Plaintiffs also assert that Dr. MacLean's opinions are unreliable because Dr. MacLean and his team did not run statistical analyses on the results. *Id.* at 14, 19.[6]

Plaintiffs' argument mischaracterizes the work of Dr. MacLean and his team. Plaintiffs ignore the fact that each PROLENE mesh sample used in the experiment was actually composed of numerous individual PROLENE fibers, each of which was subdivided into separate fiber segments due to the knit of the mesh. *See* Response Ex. C, Benight Aff. at ¶¶ 9-10. Each of these fiber segments was subjected to the same oxidation method, under the same conditions, at the same time, for the same duration. *See id.* at ¶¶ 3-4, 8. Thus, contrary to Plaintiffs' assertion that the experiment had a sample size of n=1, each sample Dr. MacLean and his team actually comprised approximately 120 fiber segments. *Id.* at ¶ 9.[7] Their analysis focused on these fiber segments. The results of their analysis would have been no different had they deconstructed each mesh sample into individual fibers, sliced each fiber into individual segments, and then proceeded through the treatment and staining processes.

Plaintiffs' assertion that Dr. MacLean should have run statistical analysis on the results reveals a misunderstanding of the purpose of statistical analysis and when it is appropriate to conduct such analyses in conducting scientific experiments. *See id.* at ¶ 11. In this case, Dr. MacLean and his team conducted the control experiment that Dr. Iakovlev failed to perform, *i.e.*, determine whether intentionally oxidized PROLENE stains with histological stain. *See, e.g.*, Motion Ex. 7, Benight Dep. at 65:19-25. Because the experiment is reproducible and showed no variability in its results (*i.e.*, none of the fibers subjected to Dr. Iakovlev's staining protocol

[6] Notably, Plaintiffs ignore the fact that neither Dr. Iakovlev nor Dr. Guelcher conducted any statistical analyses regarding their opinions in this case. *See* Motion Ex. 7, Benight Dep. at 238:18-239:7.

[7] The data and images Dr. MacLean and his team used to make this determination are contained in the laboratory documentation provided to Plaintiffs in this case.

trapped histological stain), statistical analysis was not scientifically necessary. *See* Response Ex. C, Benight Aff. at ¶ 11. Put simply, Dr. MacLean's control experiment is simply not a test on which statistical analysis would yield meaningful results. *See* Motion Ex. 7, Benight Dep. at 104:7-19; 238:5-12.

D. The Application of Analytical Techniques in the Experiment was Consistent with the Scientific Method.

Plaintiffs claim that Dr. MacLean's opinions are unreliable because the Sample 2—the sample they sent to Histion to be processed and stained according to Dr. Iakovlev's protocol—was not analyzed using SEM and FTIR. *See* Motion at 14. Plaintiffs argue that without conducting SEM and FTIR on Sample 2, Dr. MacLean could not confirm that it had actually oxidized and cracked. *See* Motion at 17. Plaintiffs' argument reveals a lack of understanding of both the experimental methodology and generally accepted scientific practice.

As an initial matter, to the extent Plaintiffs argue that Sample 2 had not actually oxidized or cracked, Plaintiffs ignore the fact that Dr. MacLean's team confirmed surface cracking in the fibers subjected to the staining protocol via optical microscopy. Indeed, various images contained in the laboratory documentation, which was provided to Plaintiffs, conclusively establish the presence of cracks on the intentionally oxidized Prolene fibers. *See, e.g.,* Response Ex. D, 2A 100x BF 0025; Response Ex. E, 2A 40x xpol 0016; Response Ex. F, 2B_0097; and Response Ex. G, 2B_0093.

In addition, there was no scientifically valid reason for Dr. MacLean's team to continue conducting SEM and FTIR analysis after they confirmed that the QUV treatment oxidized and cracked the surface of the PROLENE samples. All of the QUV-treated samples in Dr. MacLean's experiment were subjected to the same oxidative environment at the same time for the same length of time under the same conditions. *See, e.g.,* Motion Ex. 7, Benight Dep. at

254:7-23 (explaining that "[w]e processed several samples within a batch and multiple samples within that batch that were processed under the same condition, the same time, the same temperature, or in the case of the chemically oxidized protocol the same solution" and "more than one sample was either characterized with SEM and/or FTIR to show that each of the samples had been processed similarly"). Following the exposure of the samples to QUV, Dr. MacLean's team examined Samples 4, 5, and 6 using SEM, and found clear evidence of surface cracking. *Id.* at 137:19-24. Similarly, Dr. MacLean's team analyzed Samples 4 and 6 using FTIR, and found distinct evidence of oxidation. *See, e.g.*, Response Ex. H, QUV Oxidized_#4_1 (showing oxidation band at 1740 cm^{-1}, a known hallmark of oxidation).

Having demonstrated that the QUV treatment oxidized and cracked the surface of those samples, no principle of science required them to continue proving their methodology by conducting further SEM and FTIR testing. *See* Motion Ex. 7, Benight Dep. at 239:15-240:20 (explaining that additional SEM and FTIR testing was not necessary because samples subjected to identical processing under identical conditions had already been conducted); *see also id.* at 255:5-18 (explaining that sending multiple samples to Histion for processing and staining would not have yielded different results or increased the reliability of the experiment). To the contrary, subjecting the samples to such analysis introduces risk that the integrity of the samples would be compromised, potentially invalidating the experiment. *See, e.g.*, Response Ex. I, R.F. Egerton, *et al., Radiation damage in the TEM and SEM*, Micron 35, 399-409 (2004); Response Ex. J, Zankle, *et al., Assessment of Beam Damage in Polymers Caused by in situ ESEM Analysis using IR Spectroscopy*, Macromol. Symp. 265, 156–165 (2008); Response Ex. K, Perkin-Elmer Technical Note, *The Effects of Varying Force and Contact on ATR Spectra* (2012); Response Ex.

L, M. Kansiz & S. Bland, *A new "damage free" approach to defect analysis using micro ATR FTIR chemical imaging of delicate materials*, Webinar, Feb. 25, 2014.

III. Dr. MacLean Properly Relied on Ethicon's Seven-Year Dog Study

In this case, Dr. MacLean opines that PROLENE is not subject to degradation because, *inter alia*, Ethicon's Seven Year Dog Study ("Dog Study") has shown that PROLENE does not lose molecular weight *in vivo*. *See* Motion Ex. 2, General Report at 39-46 (discussing the Dog Study and results). In relevant part, the Dog Study examined the effects of long-term implantation on 5-0 PROLENE sutures by using conducting gel permeation chromatography ("GPC") on the explanted sutures. *See* Motion Ex. 6, Seven Year Data for Ten Year PROLENE Study ("Seven-Year Data"), at Eth.Mesh.09888187 (Oct. 15, 1992); Motion Ex. 5, Protocol for 10 Year *In Vivo* Study of Monofilament Sutures, at Eth.Mesh.09888071 (May 30, 1985). To determine if there had been a change in molecular weight, Ethicon compared the GPC data for the 5-0 PROLENE sutures to 4-0 sutures, which were composed of the same PROLENE resin with a diameter 50 microns larger than 5-0 sutures.[8] *See* Motion Ex. 6, Seven Year Data, at Eth.Mesh.09888187. The study shows that there was "no significant difference in molecular weight between the 4-0 PROLENE control and the seven year explant." *Id.*

Plaintiffs claim that Dr. MacLean's opinions regarding degradation should be excluded because he bases this opinion on the Dog Study. *See* Motion at 10-12. Specifically, Plaintiffs assert that the GPC data from the Dog Study is unreliable since Ethicon compared the 5-0 PROLENE suture explants to 4-0 sutures. *See* Motion at 10. Plaintiffs' argument, however, is predicated on a misunderstanding of both the concept of molecular weight and Dr. MacLean's testimony.

[8] Fifty microns is approximately half the thickness of a sheet of paper.

As Dr. MacLean explained, molecular weight is a measurement of the average size of the polymers in a particular substance. *See* Motion Ex. 1, General Report at 12; *see also* Motion Ex. 4, MacLean Dep. at 237:9-22 (explaining that molecular weight is the average length of polymer chains in a substance). Because the measurement of molecular weight is focused on the size of polymers within a specimen, the physical dimensions of the specimen itself is irrelevant to the calculation.

Applying this basic principle of polymer science to the PROLENE sutures, Dr. MacLean opined that there is no difference in the molecular weight of pristine 5-0 and 4-0 PROLENE sutures because "[i]'s the same resin formulation,[9] it's the same base polymer, [and] it has the same molecular weight coming out of the synthesis process . . . ." *Id.* at 249:21-250:4; *see also id.* at 243:22-244:2 ("I haven't seen any data that would suggest going from one filament size to the next is going to shift [the] molecular weight statistically."). He testified that this is because the "baseline molecular weight" for PROLENE is based on a "polymerization process that . . . happens well before processing" the PROLENE resin into fibers of differing sizes. *Id.* at 239:19-240:11; *see also id.* at 240:12-20 (explaining that while the extrusion process can influence a polymer, "there really shouldn't be and wouldn't be a major difference in the extrusion process between 5-0 and [4]-0 [sutures] that would influence the molecular weight").

Thus, Dr. MacLean explained that the *composition* of the substance—not its diameter—is the crucial factor identifying a proper control for molecular weight analysis. *Id.* at 239:9-13 ("Q. Okay. So you want to use the same suture, for example? A. You certainly want to use the same

[9] Dr. MacLean explained that Ethicon's slight reduction of the amount of an antioxidant in PROLENE would "not hav[e] any bearing on the molecular weight synthesis process," because "[t]hose are mutually exclusive" and there is "no interaction between those two things." *See* Motion Ex. 4, MacLean Dep. at 251:24-252:13.

material that's seen the same thermal history, processing history.") (emphasis added); *see also id.* at 247:18-248:3 ("There is not a significant enough difference between the fiber diameter of a PROLENE 4-0, 5-0, 6-0" suture "to translate into any statistical difference in the molecular weight."); *id.* at 250:5-14 (basing his opinion on his experience of "being in the plastics and polymer industry for 20 years, being around polymers that have been synthesized, that have been compounded, that have been extruded, that have been manufactured").

Having failed to identify any evidence that 5-0 PROLENE sutures could have a different molecular weight than 4-0 PROLENE sutures, Plaintiffs attempt to buttress their argument through out-of-context excerpts from Dr. MacLean's deposition. *See* Motion at 10 (pointing to Dr. MacLean's testimony that a "baseline" is necessary to assess changes in molecular weight); *id.* at 11 (including Dr. MacLean's testimony that he had not seen or requested data comparing molecular weight of 5-0 and 4-0 PROLENE sutures). But, as explained above, there was no scientific basis for acquiring separate data points to show that sutures composed of identical material have the same molecular weight. *See* Motion Ex. 4, MacLean Dep. at 251:13-21 ("I understand what good science requires. . . . And there is nothing wrong with using a 4-0 suture as a baseline here with the same exact resin formulation, same manufacturing process, to establish a baseline in the absence of a 5-0 [suture]").

Plaintiffs' arguments reflect a flawed understanding of polymer science, and should be rejected by this Court.

IV. Dr. MacLean's Molecular Weight Calculations Based On Data From Plaintiffs' Experts Are Consistent With Sound Scientific Principles.

Plaintiffs claim that Dr. MacLean's calculations of molecular weight derived from the data generated by Plaintiffs' experts are unreliable. *See* Motion at 12-13. Plaintiffs' arguments amount to nothing more than an attempt to complicate a straightforward issue.

Dr. MacLean performed a simple scientific analysis using two data sets *generated by Plaintiffs' own experts*, namely molecular weight values derived from Dr. Jordi's nano-thermal analyses and "crust" thickness values reportedly measured by Dr. Iakovlev. General Report at 54-55 (*See* Response Ex. A). Given that the data used by Dr. MacLean originated from Plaintiffs' experts' work, it is disingenuous for Plaintiffs to suggest the data points were "cherry picked" by Dr. MacLean.

As his Report demonstrates, Dr. MacLean used a valid, scientific approach based on Plaintiffs' experts' data to reliably demonstrate that if the observed "crust" layer in the Dog Study was degraded PROLENE, the associated degree of degradation (*i.e.,* losses in molecular weight) could be quantified by conventional molecular weight techniques. *See id.* These findings from Dr. MacLean's analysis are consistent with molecular weight measurements in Ethicon's Dog Study, and contradict Dr. Jordi's and Dr. Iakovlev's opinions that the crust is comprised of degraded PROLENE.

To the extent Plaintiffs disagree with Dr. MacLean's approach, analysis, or conclusions, those can be addressed through cross-examination at trial.

V. Conclusion

For the foregoing reasons, the Court should deny in its entirety Plaintiff's motion to exclude the opinions and testimony of Dr. MacLean.

Respectfully submitted,

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IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO CASE CONSOLIDATION: **Terreski Mullins, et al., v. Ethicon, Inc., et al.** **Case No. 2:12-CV-02952**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

CERTIFICATE OF SERVICE

I hereby certify that on November 9, 2015, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

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